

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1.-12. (Canceled)

13. (Currently amended) A method of ~~prevention and treatment of~~ treating asthma in a patient, which comprises instructing a patient to inhale the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient, ~~which that~~ is budesonide;  
~~characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient based on the patient's symptoms, as a treatment and a preventative measure, when the patient experiences an increase in asthma symptoms administered (i) a maintenance dose of the composition twice per day, on a regular basis, and (ii) one or more additional doses on an irregular, as-needed basis for rescue purposes, as determined by the patient.~~

14. (Previously presented) The method according to claim 13, wherein the molar ratio of (a) to (b) calculated as formoterol to budesonide is from 1:1 to 1:100.

15. (Previously presented) The method according to claim 13, wherein the first active ingredient is formoterol fumarate dihydrate.

16. (Currently amended) The method according to ~~claim 13~~ claim 13, wherein the first active ingredient is the R,R enantiomer of formoterol or a pharmaceutically acceptable salt or solvate of said enantiomer or a solvate of such a salt.

17. (Currently amended) The method according to claim ~~43~~ 15, wherein the composition is in the form of unit doses, each of which delivers a unit dose of formoterol lies in the range of from 1  $\mu$ g to 48  $\mu$ g of the first active ingredient, calculated as formoterol fumarate dihydrate.

18. (Currently amended) The method according to claim ~~43~~ 15, wherein the patient is administered an amount per day of the composition daily dose of formoterol, including for maintenance therapy, lies in the range of from that contains a total of 1  $\mu$ g to 100  $\mu$ g of the first active ingredient, calculated as formoterol fumarate dihydrate.

19. (Previously presented) The method according to claim 13, wherein the second active ingredient is the 22R epimer of budesonide.

20. (Currently amended) The method according to claim 13, wherein the composition is in the form of unit doses, each of which delivers a unit dose of budesonide lies in the range of from 20  $\mu$ g to 1600  $\mu$ g of budesonide to the patient.

21. (Currently amended) The method according to claim 13, wherein the patient is administered an amount per day of the composition daily dose of budesonide, including for maintenance therapy, lies in the range of from that contains a total of 20  $\mu$ g to 4800  $\mu$ g of budesonide.

22. (Previously presented) The method according to claim 13, wherein the particle size of the active ingredients (a) and (b) is less than 10  $\mu$ m.

23. (Previously presented) The method according to claim 13, wherein the composition additionally comprises one or more pharmaceutically acceptable additives, diluents or carriers.

24. (Currently amended) The method according to claim ~~23~~ 13, wherein the composition additionally comprises pharmaceutically acceptable additive, diluent or carrier is lactose monohydrate.

25. (Previously presented) The method according to claim 14, wherein the molar ratio of (a) to (b) calculated as formoterol to budesonide is from 1:1 to 1:70.

26. (Currently amended) The method according to claim 17, wherein the composition is in the form of unit doses, each of which delivers a unit dose of formoterol lies in the range of from 3  $\mu$ g to 12  $\mu$ g of the first active ingredient to the patient, calculated as formoterol fumarate dihydrate.

27. (Currently amended) The method according to claim 18, wherein the patient is administered an amount per day of the composition daily dose of formoterol, including maintenance therapy, lies in the range of from that contains a total of 2  $\mu$ g to 60  $\mu$ g of the first active ingredient, calculated as formoterol fumarate dihydrate.

28. (Currently amended) The method according to claim 20, wherein the composition is in the form of unit doses, each of which delivers a unit dose of budesonide lies in the range of from 50  $\mu$ g to 400  $\mu$ g of budesonide to the patient.

29. (Currently amended) The method according to claim 21, wherein the patient is administered an amount per day of the composition daily dose of budesonide, including maintenance therapy, lies in the range of from that contains a total of 30  $\mu$ g to 3200  $\mu$ g of budesonide.

30. (Canceled) ~~The method according to claim 13 further comprising instructing the patient to inhale the composition as a rescue medication.~~

31. (Canceled) ~~The method according to claim 13 further comprising instructing the patient to take a second composition, comprising a glucocorticosteroid, on a regular basis as a maintenance treatment.~~

32. (Canceled) ~~The method according to claim 13 further comprising instructing the patient to use the composition as a complement to maintenance treatment of the patient's asthma.~~

33. (Canceled) ~~The method according to claim 13 further comprising instructing the patient to inhale an effective amount of the composition as a preventive measure prior to encountering an asthma triggering event.~~

34. (Currently amended) The method of claim 33 36 wherein the asthma inducing condition triggering event is selected from the group consisting of exposure to cold air, exercise, exposure to cold air, exposure to pollen, exposure to perfume, and exposure to a smoky environment.

35. (Canceled) ~~A method of prevention and treatment of asthma, which comprises instructing a patient to inhale an effective amount of a composition comprising, in admixture:~~

~~(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and~~

~~(b) a second active ingredient, which is budesonide;~~

~~characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient based on the patient's symptoms, as a complement to maintenance treatment of the patient's asthma.~~

36. (Currently amended) A method of ~~prevention and treatment of~~ treating asthma in a patient, the method comprising which comprises

instructing a patient to inhale administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient ~~which that~~ is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient, ~~which that~~ is budesonide;

~~characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient, when the patient is expecting to encounter an asthma trigger, as a preventative measure administered (i) a maintenance dose of the composition twice per day on a~~

regular basis, and (ii) one or more additional doses on an irregular basis when the patient expects to encounter an asthma inducing condition.

37. (Canceled) ~~The method of claim 13 further comprising instructing the patient to inhale the composition daily as a maintenance treatment.~~

38. (Canceled) ~~The method of claim 13 further comprising instructing the patient to use the composition as a complement to maintenance treatment of the patient's asthma.~~

39. (Canceled) ~~The method of claim 35 further comprising instructing the patient to inhale the composition daily as the maintenance treatment.~~

40. (Canceled) ~~The method of claim 36 further comprising instructing the patient to inhale the composition on demand as a rescue medicine.~~

41. (Canceled) ~~The method of claim 36 further comprising instructing the patient to inhale the composition daily as a maintenance treatment.~~

42. (Currently amended) ~~A method of prevention and treatment of treating asthma in a patient, the method comprising which comprises~~

~~instructing a patient to inhale administering an effective amount of a composition comprising, in admixture:~~

~~(a) a first active ingredient ~~which that~~ is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and~~

~~(b) a second active ingredient, ~~which that~~ is budesonide;~~

~~characterized in that the patient is instructed to take a maintenance dose of the composition, and, if the patient experiences asthma symptoms, to inhale additional doses as needed to improve control and provide acute relief administered (i) a maintenance dose of the~~

composition twice per day on a regular basis, and (ii) one or more additional doses if and when the patient experiences an acute asthma attack.

43. (New) The method of claim 13, wherein the first and second active ingredients are both in dry powder form.

44. (New) The method of claim 13, wherein the composition is administered from a pressurized metered dose inhaler.

45. (New) The method of claim 44, wherein the first and second active ingredients are suspended in a liquid propellant.

46. (New) The method of claim 45, wherein the liquid propellant is one or more of P134a, P152a, and P227.

47. (New) The method of claim 45, wherein the liquid propellant is P227.

48. (New) The method of claim 13, wherein the composition is administered by the patient.

49. (New) A method of treating asthma in a patient, the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered (i) a maintenance dose of the composition twice per day on a regular basis, and (ii) one or more additional doses on an irregular basis when needed for symptom relief.

50. (New) A method of treating asthma in a patient, the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate of such a salt; and

(b) a second active ingredient that is budesonide;

characterized in that the patient is administered (i) a maintenance dose of the composition on a regular basis as determined by the patient's physician, and (ii) one or more additional doses on an irregular basis when the patient determines it is needed for symptom relief or when the patient expects to encounter an asthma inducing condition.

51. (New) A method of treating asthma in a patient, the method comprising administering an effective amount of a composition comprising, in admixture:

(a) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate of such a salt; and

(b) a second active ingredient that is budesonide; and

characterized in that the patient is administered one or more doses of the composition on an irregular basis when the patient determines it is needed for symptom relief or when the patient expects to encounter an asthma inducing condition.